



ISSN: 2321-2152

**IJMECE**

*International Journal of modern  
electronics and communication engineering*

E-Mail

[editor.ijmece@gmail.com](mailto:editor.ijmece@gmail.com)

[editor@ijmece.com](mailto:editor@ijmece.com)

[www.ijmece.com](http://www.ijmece.com)

## Current Status and Future Prospective For the Registration of Pharmaceutical Product in ASEAN Region

V.Mallikarjun\*, V.Rajesh Babu, M.Mounika, T.Hema Devi

**Abstract:** When it comes to regional integration efforts, the Association of Southeast Asian Nations (ASEAN) stands out as a shining example. In the face of increased worldwide rivalry and economic turmoil, it has proven to be one of the most successful regional groups of developing nations in promoting collaboration and commerce. ASEAN's transformation from a regional Association to a dynamic, integrated economic Community is at a critical juncture. For many years, ASEAN's drug regulators, industry, and worldwide organizations have worked together to establish a variety of standardized papers. The ASEAN Common Technical Dossier and the ASEAN Common Technical Requirements are two common submittal dossiers that are constantly changing. For the most part, these goals have already been achieved; the next stage will be to develop an unified placement system and mutual recognition of pharmaceutical registrations. The implementation still has a long way to go. It will be up to 2015's versioned ultimate goal of economic community to see if this is possible. A successful pharmaceutical harmonization plan has already been established in ASEAN. In the pharmaceutical business, the Association of Southeast Asian Nations (ASEAN) is playing an increasingly important role.

**Keywords:** Economic Community of the ASEAN (Association of Southeast Asian Nations).

### INTRODUCTION

The Association of Southeast Asian Nations (ASEAN) comprising the member countries, Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei Darussalam, Vietnam, Laos, Myanmar and Cambodia was established in 1967 to promote regional peace and stability. Charting the new directions, The goal is to create common regulations for pharmaceuticals in the region, reduce barriers to trade and to ensure that

pharmaceutical products penetrating the ASEAN markets show sufficient safety quality and efficacy. In my thesis I would like to explain the legal background for the establishment of harmonized pharmaceutical legislation, first experiences with the implementation and a future outlook which is the mutual recognition of marketing authorizations between the ASEAN member countries.

1 Chaitanya College of Pharmacy Education & Research, Hanamkonda, T.S.

2 MESCO College of Pharmacy, Hyderabad, Telangana State.

Corresponding Author: Dr. V. Mallikarjun

Associate Professor, Chaitanya College of Pharmacy Education & Research Hanamkonda, Telangana

E-Mail: rajeshbabuvemula@gmail.com

Finally, I want to point out in the case of Singapore, how its national registration routes can serve as an example for future pharmaceutical harmonization activities in the ASEAN region.

#### **Pre-ASEAN Southeast Asia:**

Countries that are geographically located to the south of China, east of India, and north Australia are known as Southeast Asian countries. Between China and India, it has been shaped by the two ancient civilizations. Cultural and ethnic diversity abound in the area (see map in Annex I). Southeast Asia was formerly dominated by small kingdoms and principalities, which led to continual battles and shifting borders due to land and power issues. Europe's colonialization of the region began in the 17th and 20th centuries, and the history of these countries began to develop on their own. Regardless of the ethnic diversity of the population within, all of these countries had colonies in Southeast Asia and split the territory. In the area, only Thailand was able to hold on to its independence during the colonial era.

Countries that are geographically located to the south of China, east of India, and north Australia are known as Southeast Asian countries. Between China and India, it has been shaped by the two ancient civilizations. Cultural and ethnic diversity abound in the area (see map in Annex I). Southeast Asia was formerly dominated by small kingdoms and principalities, which led to continual battles and shifting borders due to land and power issues. Europe's colonialization of the region began in the 17th and 20th centuries, and the history of these countries began to develop on their own. Regardless of the ethnic diversity of the population within, all of these countries had colonies in Southeast Asia and split the territory. In the area, only Thailand was able to hold on to its independence during the colonial era.

#### **Regional Cooperation in ASEAN:**

Founded on August 8 of that year, the Association of Southeast Asian Nations (Asean) is a regional organization that aims to promote regional stability, resolve interstate

issues, and safeguard member states from communist expansion and insurgencies within their own borders. An idealistic assertion of intent is contained within the statement. It stresses the need of 'solidarity and cooperation', of 'equality and partnership', and of 'peace, progress, and prosperity' in the pursuit for 'solidarity and cooperation'. This also emphasizes the importance of maintaining national identities and avoiding 'foreign influence to undermine the national freedom of the states'. This means that ASEAN can be viewed as an inter-governmental body and that the sovereignty of the states must be maintained. The proclamation concludes by making it clear that the association's membership is available to all countries in Southeast Asia. Brunei joined ASEAN on January 8, 1984, just a few years after gaining its independence. Because they were the founding members of ASEAN, Brunei, Indonesia, Malaysia, the Philippines, Singapore, and Thailand are commonly referred to as the ASEAN-6. Vietnam became an ASEAN member state on July 28, 1995 as a result of the conclusion of the Cold War. On July 23, 1997, Laos and Myanmar (synonymous with Burma) joined the organization. On April 30th, 1999, Cambodia became a member of the ASEAN community. The CLMV-group refers to the four countries that joined ASEAN about a decade after the original founding members did so.

At the time of membership, they were required to embrace all ASEAN agreements, although they were given additional time to meet their goals. On 28 July 2006, East Timor requested ASEAN membership as an observer state, a status it had held since its independence from Indonesia in 2002. Around 2011, the ASEAN membership will come into effect. A observer status has been granted to Papua-Neuginea since 1985. An ethnic secessionist movement that threatened territorial integrity and a communist insurgency that threatened regime security were among the difficulties that ASEAN's founding members faced when they became independent after

independence from colonial rule. Political and strategic dynamics in Southwest Asia have changed dramatically since the Cold War ended. Due to the need for a fresh emphasis, ASEAN resolved to develop and encourage initiatives aimed at increasing regional and international economic cooperation. ASEAN's member states were undergoing political reform, liberalization, and economic expansion in the following years. An example of regional collaboration was given by ASEAN. At the same time, since ASEAN's founding in 1967, member states have avoided turning regional conflicts into armed war, which is a major accomplishment. For the ASEAN governments, the 1997-98 Asian economic crisis and inflation presented a new set of challenges, exacerbated by financial deterioration and the accompanying political and social turmoil. Associations also had to contend with the accession of members from less developed semi-authoritarian governments. As a result of the globalization process, ASEAN has to take new steps in order

to strengthen its economic and commercial competitiveness (Actual trade indicators are listed in Table 1). ASEAN resolved that the ASEAN Community shall be established comprising three pillars for regional integration, namely:

②

ASEAN's Security Community, under the purview of ASEAN's Foreign Affairs Ministers

②

ASEAN's Economic Community (AEC) under the purview of ASEAN's Economic (Trade) Ministers

②

ASEAN's Socio-Cultural Community (ASCC) under the purview of ASEAN's Foreign Affairs Ministers. Worthwhile to mention is that through the Bali Concord II in 2003, ASEAN has subscribed to the notion of democratic peace, which means all member countries believe democratic processes will promote regional peace and stability. Also, thenon-democratic members agreed that it was something all member states should aspire to.

**Table 1: Selected basic indicators for the ASEAN region in 2006 (ASEAN Secretariat)**

Basic indicator	Size
Land Area	4465500 km <sup>2</sup>
Population	567390000 people
Annual popul. Growth	1.6%
GDP total	1064351.3 million US\$
Total trade	1442656.9 million US\$
Foreign direct Investment	38082.9 million US\$

### **Regulatory authorities of ASEAN countries:**

#### **Malaysia:**

Under Malaysia's Ministry of Health (MOH) are the Medical Device Bureau (MDB) and the National

Pharmaceutical Control Bureau (NPCB). The MDB ensures the quality, safety and efficacy of medical devices in Malaysia, while the NPCB does the same for pharmaceuticals. Both bodies are also responsible for setting laws and standards, registering health products and issuing licenses to manufacturers, distributors, importers and exporters.

#### **Philippines:**

The Department of Health (DOH) is the main health agency in the Philippines. The DOH oversees access and quality of public health services and regulates providers of health goods and services. In addition to the DOH, the Philippine Food and Drug Administration (FDA) was established in 2009 to replace the Bureau of Food and Drugs (BFAD). The FDA has the power to immediately recall, ban, or withdraw medical products that fail safety standards or are found to pose a threat

to the public. In addition, the agency will be authorized to inspect facilities for compliance and seize products that have safety issues.

#### **Singapore:**

The Health Sciences Authority (HSA) was established in 2001 to regulate health products and oversee public health issues in Singapore. Under the HSA is the Health Products Regulation Group (HPRG), which is a body that ensures that drugs, medical devices and other health products are regulated to meet quality, safety and efficacy standards.

#### **Thailand:**

The Food and Drug Administration of Thailand (FDA Thailand) is the organization responsible for the safety, quality and efficacy of pharmaceuticals and medical devices in Thailand. This organization is split into two divisions, the Support Division and the Health Product Control Division. The Bureau of Drug Control (BDC) and the Bureau of Medical Device Control (BMDC) operate under the latter. These are each responsible for the development and review processes of products within their remit. Regulatory policy and enforcement are handled by committees under the FDA.

#### **Vietnam:**

Under Vietnam's Ministry of Health (MOH), the Drug Administration of Vietnam (DAV) is responsible for the regulation of pharmaceuticals, and the Department of Medical Equipment and Health Works (DMEHW) is responsible for the regulation of medical devices. The DAV evaluates pharmaceutical applications for their compliance with the 2005 Pharmaceutical Law and issues licenses accordingly. The DMEHW handles product registration and evaluation for medical devices.

#### **Burma:**

When it comes to food safety in Myanmar, which just became a more market-oriented economy, there is a lot of work to be done because food commodities are now being exported and imported in large quantities. In

spite of the fact that food control efforts have been around since the pre-war era, systematic methods have only recently been used.

- The FDA was created in 1995, and the National Food Law was enacted in 1997. We're working on notifying you.

Since 2000, the FDA's Upper Myanmar Division has been in operation.

- The most significant limitation is the lack of functional capabilities.

Central Epidemiological Unit (CEU) data suggests that the health authorities should pay more attention to food safety, particularly in terms of sanitary conditions.

- As a result, food safety and sanitation training and survey programs have been developed and many more are in the works.

In order to comply with HACCP-based Food Hygienic Practice on food inspection, FDA requires Myanmar's food manufacturers to follow the guidelines in this document.

When formulating national standards, policies, and guidelines, the FDA relies on the Codex Alimentarius Commission's working materials as an interim measure.

- The food control authority realized that Risk Analysis Approach is of our concern and pre and post market surveillance are regularly conducted to assess quality and safety of food for public.

#### **Pharmaceutical market in ASEAN region:**

All 10 ASEAN member countries – Brunei, Burma, Cambodia – have pharmaceutical businesses that are in varied levels of development compared to the rest of the region. For example, the Indonesian pharmaceutical industry expects this year's growth to be lower than the recent yearly increases of over 12 percent, falling to 9 percent. A whopping 95% of locally produced goods are sold in the country of origin, with 70% of all businesses being owned and operated by citizens. In Malaysia, sales are predicted to expand at a rate of over 11% per year and reach over \$1.8 billion by 2012,

according to research firm Research and Markets.

## **METHODOLOGY**

The research was carried out with the collected data by analyzing the terms of the below parameters :

### **Types of study**

The study was conducted with an objective to check out the regulatory framework for pharmaceutical products registration in ASEAN countries.

The major emphasis has been provided to regulate requirements of ASEAN market.

All the required guidelines have been pooled up and translated from their local language to English which are studied and made understandable pertaining to pharmaceutical products in ASEAN.

### **ASEAN's Institutional Framework:**

#### **Decision Making Process:**

Because there are no supranational institutions to set policy or set laws and regulations on behalf of the ASEAN members, the region is merely a loose confederation. Except for those mutually agreed upon via ASEAN cooperation initiatives, each member nation has its own separate legal system and laws and policies. Every ASEAN program is the result of a collective agreement among the member countries. The Summit, an annual gathering of ASEAN's heads of state and government, is the organization's highest decision-making body. Other regional choices are made by the several ministerial bodies, each of which has been given specific responsibilities. Formal and informal ministerial meetings, such as the ASEAN Ministerial Meeting of Foreign Ministers (AMM), the ASEAN Economic Ministers Meeting (AEM), the ASEAN Ministerial Meeting on Health, Social Welfare, and Science and Technology (MMHSWT), bring together 17 levels of government. 29 committees of senior officials and 122 technical working groups and task forces support ASEAN activities at the ministerial level. Each year, they gather in preparation for their respective higher-level meetings, where the recommendations are supported

and choices are made. They undertake the preoperative work.

#### **ASEAN way:**

ASEAN's general attitude is to make decisions based on consultation (musjawarah) and consensus-finding (mufakat) by all members of the organization. This political system is based on a Javanese tradition. As a result of the ASEAN approach, all relevant issues are addressed and argued until a final agreement with mutual acceptance is reached. To reach an agreement, there is no vote process but only an open discourse. The "ASEAN-X" principle governs decision implementation. People who are ready to move forward with liberalization won't be held back by those who aren't.

#### **Crisis Management and Disputes:**

Originally the provision for resolution of disputes regarding enforcement of agreements was that of the 1976 Treaty of Amity and Cooperation which encouraged the ASEAN member states to find a solution through diplomatic negotiations (ASEAN way). Recently ASEAN has shifted to the WTO style<sup>13</sup> by concluding to a Protocol on Enhanced Dispute

Settlements Mechanism<sup>14</sup> which helps resolving issues, which are related to economic agreements. Member states which are party to a dispute may at any time agree to good offices, conciliation or mediation. In case member countries cannot agree on the subject matter on implementing ASEAN agreements, the dispute is referred to the Senior Economic Officials meeting (SEMO) for ruling. The parties to the dispute may appeal the ruling by SEMO to the ASEAN Economic Ministers (AEM) appeal body, which will make a final decision. Compensation and the suspension of the concession will apply to the party which failed to comply with the decision.

#### **Summit:**

Until now the highest decision-making body of ASEAN is the meeting of ASEAN Heads of Government also known as the ASEAN Summit. These are annual meetings taking place usually in autumn. The first summit was in 1976 and the

following summits taking place infrequently. Since 2001 it was decided to meet yearly to address urgent issues affecting the region.

#### **The sequence of**

#### **the meetings is usually as follows:**

Prior to the summit there were various meetings at the level of senior officials and the ASEAN Directors – General.

These are followed by Joint Ministerial Meetings of the Foreign and Economics Ministers of ASEAN and if needed with the respective counterparts from their so-called dialogue partner countries.

During the formal Summit ASEAN leaders meet to take decisions for the region. These are followed by bilateral or plenary session meetings between ASEAN leaders with their dialogue partner countries. In total ASEAN have eleven dialogue partners, namely Australia, Canada, China, European Union, India, Japan, New Zealand, Republic of Korea, the Russian Federation, the United States and the United Nations. These are followed by joint dialogue meetings of the ASEAN+3 meeting of ASEAN with China, Japan and South Korea. The biggest dialogue meeting is the East Asian Summit between ASEAN, China, Japan, South Korea, Australia and New Zealand and India, which is established since 2005.

During the summits and the preceding meetings intra- and inter-ASEAN agreements are signed. Further updates on progress of action plans and programs are presented and decisions are taken. Throughout the year the different ASEAN bodies, committees and working groups work towards the targets set out in these agreements.

#### **Secretariat of ASEAN:**

ASEAN's general attitude is to make decisions based on consultation (*musjawarah*) and consensus-finding (*mufakat*) by all members of the organization. This political system is based on a Javanese tradition. As a result of the ASEAN approach, all relevant issues are

addressed and argued until a final agreement with mutual acceptance is reached. To reach an agreement, there is no vote process but only an open discourse. The "ASEAN-X" principle governs decision implementation. People who are ready to move forward with liberalization won't be held back by those who aren't.

#### **Committees in Third Countries:**

ASEAN has established committees in its 'Dialogue Partner' countries to handle ASEAN's external relations with these countries in international organizations. These committees comprise of ambassadors of all ASEAN Member Countries based in the capitals of the third countries. They conduct consultative meetings with their host government.

#### **Standing Committee:**

The ASEAN Standing Committee (ASC) is composed of the Directors-

General of the ASEAN Departments of the respective Ministries of Foreign Affairs. The Directors-General meet as a body standing in for the ASEAN foreign ministers who meet in the ASEAN Ministerial Meetings (AMM). Chairman of the ASC is the foreign minister of the summit's host country.

#### **Ministerial Sectors:**

There are various ministerial sectors and its meetings reporting jointly to the ASEAN leaders. Supporting these ministerial bodies are committees of senior officials, technical working groups and task forces. The 17 ministerial sectors come together at formal or informal ministerial meetings out of which the ASEAN Ministerial Meeting (AMM) and the ASEAN Economic Ministerial Meetings (AEMM) are the most important ones.

ASEAN Economic Ministers (AEM) is in charge for the pillar economic community. Under the purview of the AEM are its subordinated committees and working groups and its regular meetings such as the Senior Economic Officials Meeting (SEOM), Asian Convulsive Committee on Standards and Quality

Meetings and Product Working Groups-Meetings (ACCSQ).



**Figure1:OrganizationalStructureofASEANAEMASEANEconomicMinisters**

AMM

## ASEAN

Ministerial

MeetingSEOMSeniorEconomicOfficialsMeetingASCASEANStandingCommittee

SOMSeniorOfficialsMeeting

ACCSQ ASEAN Consultative Committee on Standards and Quality  
WG Working Group

### The ASEAN Charter as Future Institution:

Foreign Ministers have established a High Level Task Force (HLTF) to prepare the first draft of the ASEAN charter, which is expected to be completed by the end of 2007. The Eminent Person Group's recommendations are taken into account by the HLTF while crafting the charter (EPG). Senior statesmen on the EPG are in touch with a variety of stakeholders<sup>20</sup>, including members of civic society, business, and academia. Report on ASEAN Charter<sup>21</sup> was delivered during 12th Summit in January 2007.

**Economic Integration on the Healthcare Sector:**  
Under the purview of the ASEANs Economic Ministers (AEM) is the pillar Economic Cooperation with the aim to establish one ASEAN Economic Community (AEC). Economic integration activities are to strengthen the implementation of its existing economic initiatives including the ASEAN Free Trade Area (AFTA), ASEAN Framework Agreement on Services, ASEAN Investment Area, Dispute Settlement and the initiative for ASEAN integration of the CLMV accession countries.

### Elimination of Technical Barriers Trade:

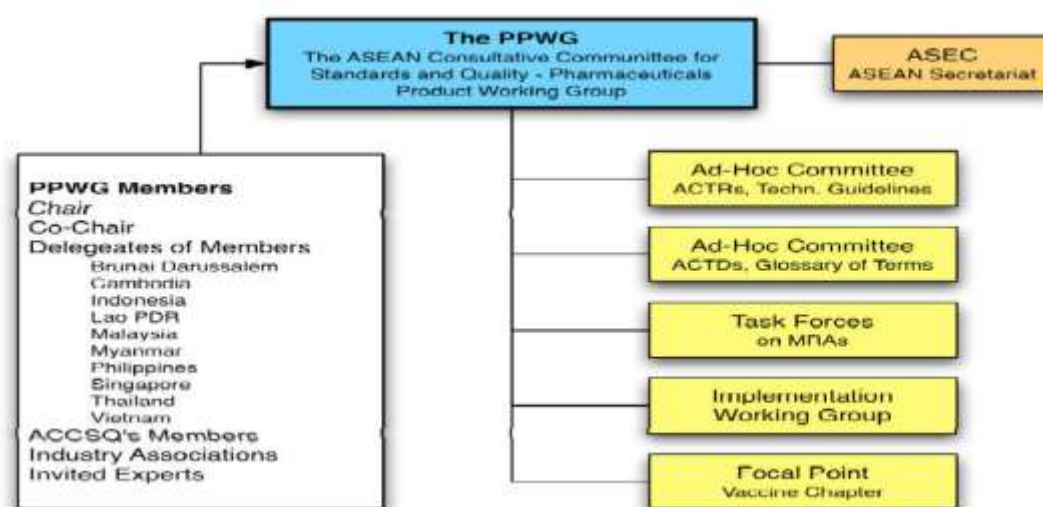
One of the Committees under ASEAN Economic Ministers is the ASEAN Consultative Committee on Standards and Quality (ACCSQ) that was formed in 1992 to support and complement the ASEAN Free Trade Area (AFTA). ACCSQ meetings are twice a year around March and August. The primary objective of ACCSQ is to facilitate trade and to eliminate technical barriers to trade. It is often the duplicative test procedures arising from different systems of conformity assessment in various countries that have become serious barriers to trade. The Committee and its working group strive to harmonize national standards with 13 international standards and implement mutual recognition arrangements on conformity assessment.

## ASEAN's Regulation on Pharmaceuticals:

In March 1997, the 13th.ACCSQ meeting recognized the need for a Pharmaceutical Product Working Group, which was established. As a result of Malaysia's efforts, the relevant bodies endorsed a proposal. On Sept. 29, 1999, Malaysia chaired the PPWG and Thailand was its co-chair. It is the primary goal of the PPWG to build a harmonized regulatory framework for pharmaceuticals around the world. In the end, the goal is to remove all barriers to trade, but to ensure that all pharmaceutical items entering the ASEAN market are safe, effective, and of high quality.

It is customary for industry representatives from local trade associations to speak up during PPWG meetings in order to be heard by officials of the Health Authority. Recently, the PPWG has become the conduit through which two 'regional' trade groups have conducted discussion between health authorities and industry. Both the ASEAN Pharmaceutical Club (APC) and the ASEAN Pharmaceutical Research Industry Organisations (APRIA), both of which are made up of members from regional generic

trade associations, and the ASEAN Pharmaceutical Club (APC). Three months prior to the PPWG meetings, the PPWG Chair will receive position papers from regional industry organisations. In the past, there were multiple trade organizations operating in each country. It took a long time to reach an agreement among the various trade associations. In order to attend meetings of the PPWG, observers from industry need to contact their local trade association. According to the host country's



**Figure2:PPWGMeetingsOrganizationalStructure**

### ConsultationProcedure

For the sake of reflecting the three factors that underlie the approval of pharmaceuticals, the PPWG determined that the themes selected for harmonization would be separated into Safety, Quality, and Efficacy (SQE). Each harmonization item will be discussed in detail in ad hoc expert working groups and committees, as agreed. The working groups should take into account the needs of national regulatory agencies and sound international regulatory principles, but not over-regulation or merely adopting systems of reference agencies, in order to avoid over-regulation.

It was important to design an operational procedure that leads to an efficient work program in order to develop a harmonization of pharmaceutical rules.

In order to identify the issues that need to be addressed, the PPWG devised the following consultation approach.

To begin, ASEAN member countries should share and examine information on current pharmaceutical standards and legislation.

ASEAN rules and international accepted standards, such as ICH and WHO guidelines, should be compared.

ASEAN's "Key areas" for harmonization have been identified via surveys and comparative research.

As part of the PPWG, each harmonization subject has a designated lead country, as well as ad-hoc and/or permanent working groups to discuss the scientific and technical

elements. Working groups will create a draft plan for how to unify the designated core area. ASEAN has to evaluate whether international guidance texts are relevant to the SEAN region. ASEAN will create its own guidelines if the world community does not provide any, or if the international guidance does not apply to the area. The working groups are engaged in open discussions with industry leaders and international specialists. At the PPWG meeting, the lead country of the working groups presents the proposed harmonization of a major topic for discussion and agreement. ASEAN health authorities and their respective national industry associations are notified if there are any objections to the draft and subsequent amendments.

1. Taking into account input from health authorities and industry, the leading country is entrusted with revising the ideas in question. The final text is agreed upon by regulators of ASEAN at the PPWG sessions once consensus has been established. Agreements are reached when all member states agree to them. Occasionally, Myanmar representatives were unable to attend the PPWG meetings, therefore they sent their positions via letter.

2. PPWG's final draft is sent to the appropriate higher entities for approval or decision-making.

3. There are clearly defined deadlines for implementing these harmonization decisions. Following the national protocols, implementation is carried out and overseen by the working group's respective lead country. The PPWG informs the ACCSQ of their accomplishments. All PPWQ meetings have an ASEAN secretariat delegate present to facilitate communication and connections with other ASEAN organizations. The ASEAN-homepage Secretariat's and each health authority's homepage should be updated with new regulatory ASEAN recommendations.

4. Training, assistance, and evaluation are all part of the implementation process. PPWG collaborates with

Regional and global organizations have worked together to harmonize many aspects of drug regulation activity throughout the last ten years. The main motivation for harmonizing pharmaceutical rules is to make drugs more widely available and to meet the demands of global trade by establishing uniform standards for safety, quality, and efficacy. Therapeutic advancements are expected to be made more quickly and at a lesser cost if needless regulatory regulations are eliminated. Drug registration processes, pharmaceutical inspection services, and certified conformity with good manufacturing practices are all prerequisites for any coordinated approach to international drug regulation. In March 1997, the 13th.ACCSQ meeting recognized the need for a Pharmaceutical Product Working Group, which was established. As a result of Malaysia's efforts, the relevant bodies endorsed a proposal. On Sept. 29, 1999, Malaysia chaired the PPWG and Thailand was its co-chair.

The main objective of the PPWG is to develop a harmonization scheme of pharmaceutical regulation. The ultimate goal is to eliminate technical barriers to trade, however ensuring those pharmaceutical products penetrating the ASEAN market are safe, efficacious and of quality.

The challenge of ASEAN was to define regional accepted standards for pharmaceutical harmonisation on which facilitates intra and inter-ASEAN trade of pharmaceuticals. It is a great challenge to develop standards for the region that are appreciated by trade partners and that encourage foreign direct investment. Especially as some of the CVLM countries are still regarded as developing countries.

The ASEAN countries had to define their regional standards by taking into account available international guidelines. The aim of the existing international standards hereby varies.

## RESULTS&DISCUSSIONS

ICH was established in 1990 with the aim to create harmonized guidelines for the drug development of innovative products for research-based industries in the tripartite region (US, EU, Japan). These are all high-income countries. Therefore, the ICH commissioned the generic industry as they were not within the scope of ICH. The ICH guidelines do not address specific requirements for categories of products and therefore they are valid for all pharmaceutical products (NCE, Biotech, Generics, essential drugs, orphan drugs, etc.).

Anyhow, ICH advocacy seminars have been held in different regions of the world and participating countries look at ICH guidelines as the international norm or gold standard even if they are not affordable or reachable by some of the low-developing countries. Further to mention in the context is that ICH Guidelines cannot be automatically applied to all countries in the world that are ICH countries. (e.g. stability discussion section 4.2.1)

WHO aspires to develop worldwide standards for the promotion and protection of public health in non-ICH nations with a mandate of 191 member states (=85 percent of the world's population). These requirements should ensure that pharmaceuticals are safe, effective, and of a high enough degree of quality and effectiveness. The World Health Organization (WHO) seeks to avoid unreasonably high requirements that would make pharmaceutical items prohibitively expensive for local public health. Local or generic manufacturers in several countries provide vital pharmaceuticals for the prevention and treatment of locally endemic illnesses. It would be significantly worse for the public's health if these pharmaceuticals were withdrawn because they couldn't meet hypothetical quality requirements set by the International Conference on Harmonisation (ICH). People are worried that the ICH and WHO would create two sets of norms for drug regulatory harmonization, one for wealthy countries and one for less wealthy ones, by

setting separate requirements for the process of harmonization.

A decision was made in 1997 to continue harmonizing ICH efforts after the majority of them had been completed. Existing rules were updated to provide provisions for worldwide harmonization and up-to-date information. Following WHO and proposals from Regional Harmonization Initiatives (non-ICH countries), the ICH-Global Coordination Group (GCG) was formed in 2003. Finalized ICH guidelines are the goal of the GCG, and they hope that non-ICH countries will adopt them as well.

Harmonization outside regional boundaries can be considered as a further step toward globalization harmonization, which aims to prevent redundant or conflicting norms. ICH is expanding its membership and focus from the ICH region to other regional initiatives in order to better understand the impact of globalization. It is the goal of the Singapore health authority to become a center of excellence in ASEAN for biologics and biotechnological products.

In this respect, they continue to strengthen the regulatory framework to create an environment to support the development of biomedical science in Singapore. Further internal capabilities for the evaluation of these products are envisaged, by closer collaboration with benchmark agencies.

## CONCLUSION

Because of globalization, strategic partnerships have become increasingly important. Trade and investment can be facilitated and liberalized with the help of harmonized standards. Only through bridging the gaps between ASEAN member nations in the construction of regulatory systems and the fulfillment of shared requirements can regional harmonization be accomplished. International recognition is made possible through global cooperation, which opens up new possibilities for growth and advancement. In order to achieve real harmonization, MRA must be established.

PPWG will continue its efforts to create a single pharmaceutical market, notwithstanding obstacles.

## REFERENCES

1        1 The Manila Pakt is an informal collective defense treaty signed in 1954 by the Southeast Asian Treaty Organization (SEATO) between Australia, France, New Zealand, Pakistan, the Philippines, Thailand, the United Kingdom, and the United States. First, we have Shaune, who is mentioned in the section below. b) A. Murphy; (2002). Malaysian independence and the formation of the Association of Southeast Asian Nations (ASEAN) triggered a series of conflicts in Southeast Asia that lasted from 1961 to 1967. c) M. Leifert (1989), ASEAN and the Security of Southeast Asia, London, Routledge, d) Dorsch, J.; Wagner, C. (1999) "ASEAN and SAARC: Development and Prospects for Regional Collaboration in Asia," Abera Academic Press, Inc.

2        Ministers of Foreign Affairs from the Association of Southeast Asian Nations (1967) In a statement issued by ASEAN Sec (<http://www.aseansec.org/1212.htm>), the ASEAN Declaration

3        At the Singapore Institute of Southeast Asian Studies, Collins A. (2003), "Security in Southeast Asia: Regional and Global Issues," 128 pages

4        5 ASEAN Leaders (1997) "ASEAN Vision 2020"; signed during the 2nd Informal ASEAN Summit, and published at the ASEAN Secunder <http://www.aseansec.org/5228.htm>.

5        6 ASEAN Heads of State and Government (2005) The ASEAN Summit in 2005

6        "Declaration of the ASEAN Concorde II," 9th ASEAN Summit, ASEAN Sec, <http://www.aseansec.org/15159.htm>

7        The Declaration of ASEAN Concorde II was signed by 14 ASEAN leaders in 2003. <http://www.aseansec.org/15159.htm>

8        As of 2007, the ASEAN Secretariat issued a "Organizational Chart and

Description" at <http://www.aseansec.org/13103.htm>.

9        For example, the ASEAN Sec. (2007) "Chairmen of the Summits," "ASC, and AMM," was released by the ASEAN Sec.

10       The ASEAN Secretariat publishes all 17 ASEAN Summit documents, including agreements, treasuries, and reports, at <http://www.aseansec.org/4933.htm>.